ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1180 (consolidated with 24-1178)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE ETHYLENE OXIDE STERILIZATION ASSOCIATION, INC.,
Petitioner,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents.

On Petition for Review of Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 24,090 (April 5, 2024)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER AND VACATUR

Charles H. Knauss
Matthew Z. Leopold
HUNTON ANDREWS KURTH LLP
2200 Pennsylvania Ave. NW
Washington, DC 20037

Andrew R. Varcoe
Christopher J. Walker
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

Trevor S. Cox
Counsel of Record
J. Pierce Lamberson
HUNTON ANDREWS KURTH LLP
951 East Byrd Street, East Tower
Richmond, VA 23219
(804) 788-8200
tcox@huntonak.com

Counsel for Amicus Curiae

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with D.C. Circuit Rule 28(a)(1), *amicus curiae* states as follows:

A. Parties, Intervenors, and *Amici Curiae*

These cases involve the following parties:

Petitioners:

No. 24-1178: California Communities Against Toxics, Clean Power Lake County, Comite Dialogo Ambiental, Inc., Rio Grande International Study Center, Sierra Club, and Union of Concerned Scientists.

No. 24-1180: The Ethylene Oxide Sterilization Association, Inc.

Respondents:

Respondents are the U.S. Environmental Protection Agency and Michael S. Regan, Administrator, U.S. Environmental Protection Agency (in Nos. 24-1178 and 24-1180).

Intervenors and *Amici Curiae*:

California Communities Against Toxics, Clean Power Lake County, Comite Dialogo Ambiental, Inc., Rio Grande International Study Center, Sierra Club, and Union of Concerned Scientists are Intervenors for Respondents in No. 24-1180. The Ethylene Oxide Sterilization Association, Inc. is Intervenor for Respondents in No.

24-1178. The American Petroleum Institute is the only other *amicus curiae* at the time of this filing.

B. Rulings Under Review

These consolidated cases involve final agency action of the United States Environmental Protection Agency titled "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review," published at 89 Fed. Reg. 24,090 (Apr. 5, 2024).

C. Related Cases

Two consolidated cases (Case Nos. 24-1178, 24-1180) seek review of the agency action challenged here. *Amicus curiae* is unaware of any other related cases.

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

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GLOSSARY OF TERMS

Act	Clean Air Act
Agency	U.S. Environmental Protection Agency
APA	Administrative Procedure Act
CAA	Clean Air Act
Chamber	Chamber of Commerce of the United States of America
EPA	U.S. Environmental Protection Agency
EtO	Ethylene Oxide
MACT	Maximum Achievable Control Technology
NESHAP	National Emission Standards for Hazardous Air Pollutants
Rule	"National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review," 89 Fed. Reg. 24,090 (Apr. 5, 2024)

INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation.[1] It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the business community.

The rule challenged in this case—"National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review," 89 Fed. Reg. 24,090 (April 5, 2024) ("Rule")—will impact producers, users, and downstream beneficiaries of ethylene oxide. Ethylene oxide is a gas used to make chemicals and sterilize equipment and food products. *See* EPA, Toxic Release Inventory National Analysis, Ethylene Oxide Releases Trend (March 2024), https://tinyurl.com/ywmfec5r. Importantly, ethylene oxide helps maintain an adequate supply of life-saving

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from the Chamber, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The Chamber has filed an unopposed motion for leave to file this brief.

medical devices. About half of all medical devices in the U.S. are sterilized with ethylene oxide. U.S. Food & Drug Administration, Sterilization for Medical Devices (Sept. 26, 2024), https://tinyurl.com/6kk259hk. "For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process." *Id.*

The Chamber is well positioned to aid this Court's review of the Rule. The Chamber's members include businesses from all sectors of the economy that stand to be impacted by the Rule and by the interpretation of the Clean Air Act that the Rule advances. These include ethylene oxide manufacturers, owners and operators of commercial sterilization facilities, medical device manufacturers, health care providers, food producers, and others that benefit from ethylene oxide sterilization. More broadly, the Chamber represents businesses that have a strong interest in properly construing regulatory statutes and in ensuring that administrative agencies act within their statutory authority.

While the Chamber supports appropriately tailored regulations and the protection of public health, performance by the Environmental Protection Agency ("EPA" or "Agency") of a second "residual risk review" for hazardous air pollutants, including ethylene oxide, under Clean Air Act section 112(f)(2) is unlawful. Section 112(f)(2) is a limited grant of authority to perform a one-time residual risk review (following the initial setting of standards under section 112(d) of the Act), which

serves as a back-up plan to further congressional action. Section 112(f)(2) was never meant to authorize perpetual, open-ended regulation by the EPA, which would overlap and interfere with the periodic reviews that Congress required in section 112(d)(6) of the Act. If accepted, EPA's attempt to enlarge its limited authority under section 112(f)(2) could be used to encourage unpredictable, counterproductive regulation in other areas. The Chamber has a strong interest in promoting a predictable regulatory environment through advocating for the sound interpretation of statutory grants of authority to regulatory agencies, on which the Chamber's members rely to invest in and grow their businesses.

INTRODUCTION

The Clean Air Act ("CAA" or "Act") establishes a two-step process for initially regulating categories of sources of hazardous air pollutants. At the first step, the Act directs EPA to issue technology-based standards for each source category that are designed to achieve maximum emissions controls for major sources of pollutants through application of technologies used by the best-performing sources in each category. These standards, governed by section 112(d) of the Act, are the focus of the program and are appropriately referred to as Maximum Achievable Control Technology ("MACT") standards. Congress set forth detailed directions and a precise, 10-year schedule for establishing MACT standards. 42 U.S.C. §§ 7412(d)(2)–(3), (e). And, importantly, section 112(d)(6) of the Act provides for

periodic technology-based review and, when needed, revisions of the section 112(d) standards, to be performed at least once every 8 years for each source category being regulated. Under section 112(d)(6), EPA has reviewed and revised several of its 112(d) standards. *See* EPA, Risk and Technology Review of the National Emissions Standards for Hazardous Air Pollutants (last updated Aug. 26, 2024), https://tinyurl.com/muz9dy46.

At the second step, after EPA issues technology-based standards for a source category, the Act outlines a process for assessing any risk from pollutants that might remain from that source category. This step—commonly known as the "residual risk review" step—is governed by section 112(f) of the Act, and instructs EPA to prepare a report for Congress with recommendations for legislation on residual risks. In the event that Congress fails to act on EPA's recommendations, section 112(f)(2) provides a contingency plan—it requires EPA to evaluate and, if appropriate, promulgate so-called "residual risk standards" for a source category within 8 years of the promulgation of the technology-based standards that EPA set for that category under section 112(d). Unlike the technology-focused section 112(d), section 112(f)(2) provides for risk-based standards. Also unlike section 112(d), section 112(f)(2) does not authorize EPA to do any additional rounds of review and regulation.

Because Congress never acted on EPA's report, EPA has performed one-time "residual risk reviews" for dozens of source categories under section 112(f) over the last quarter-century. Until now, EPA has never, in the program's thirty-four-year history, performed a *second* residual risk review for a source category. Then came the Rule. EPA's novel attempt to conduct a second residual risk review for ethylene oxide sterilizers rests on a fundamental misinterpretation of its own authority under section 112(f)(2) of the Act. As the context and structure of section 112(f) make clear, section 112(f)(2) represents a limited grant of one-time residual authority that serves as a second-best alternative to further congressional action. It was never meant to grant EPA the massive, open-ended authority to repeat the residual-risk-review process for a source category at the Agency's discretion.

Allowing EPA to convert a statutory back-up plan into a free-ranging license to regulate would cause major uncertainty for regulated businesses. Businesses require stable, predictable regulations to plan for the future and make long-term investments. EPA's novel and unbounded assertion of authority under section 112(f)(2) portends the prospect of regulation under section 112(f)(2) that could come at any time and in any form. In this particular instance, it risks driving ethylene oxide producers and the businesses that rely on them out of the country or out of business altogether. But the same risk exists for producers, users, and downstream beneficiaries of other substances subject to section 112 of the Clean Air Act. *See*

EPA, National Emission Standards for Hazardous Air Pollutants (NESHAP) (last updated July 2024), https://tinyurl.com/mxc7rbks (listing over 140 source categories that EPA has established under section 112). Moreover, if accepted by this Court, EPA's bold assertion of power under section 112(f)(2) could have relevance to other statutory contexts, well beyond the domain of environmental regulation.

Because EPA lacked authority to perform a second residual risk review under section 112(f)(2), the Court should vacate the Rule.[2]

ARGUMENT

I. Clean Air Act section 112(f) is not an open-ended grant of continuing authority to regulate.

The Administrative Procedure Act ("APA") requires courts to "set aside agency action[s]" that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). The role of this Court, in reviewing the Rule under the APA and the Clean Air Act, is "to independently interpret the statute and effectuate the will of Congress subject to constitutional limits." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2263 (2024); *see also United States Sugar Corp. v. EPA*, 113 F.4th 984, 991 n.7 (D.C. Cir. 2024) (explaining that *Loper Bright* "controls EPA interpretations of the Clean

[2] The Chamber agrees with Petitioner Ethylene Oxide Sterilization Association that the Rule is invalid on other grounds, but this brief focuses on the section 112(f)(2) issue and on the impacts of EPA's incorrect interpretation of that provision.

Air Act" because "judicial review under the Clean Air Act is 'essentially the same' as judicial review under the APA") (citation omitted).

The Court cannot uphold EPA's interpretation of section 112(f) unless, after "applying all relevant interpretive tools," it determines that EPA's reading is the "single, best meaning" of the provision. *Loper Bright*, 144 S. Ct. at 2266; *see also United States Sugar Corp*, 113 F.4th at 991 (same). Questions of "the scope of an agency's own power" pursuant to a statute present "perhaps the occasion on which abdication in favor of the agency is *least* appropriate." *Loper Bright*, 144 S. Ct. at 2266 (emphasis original).

Here, EPA's interpretation of its own power under section 112(f)(2) is far from the best reading of the provision. The Rule is arbitrary and capricious and should be set aside.

A. Section 112(f)(2) is a limited grant of residual authority permitting EPA to perform a one-time assessment of residual risk review.

Contrary to EPA's position that section 112(f)(2) permits multiple reviews for the same source category, section 112(f)(2) is a limited grant of one-time authority that serves as a back-up to further congressional action. This provision was never meant to license EPA to engage in repeated residual risk reviews of the same hazardous-air-pollutant standards.

1. Section 112(f)(2) spells out a back-up plan if Congress fails to act.

In 1990, Congress authorized EPA to prepare a one-time report on risks that might remain after regulated parties applied technology-based Maximum Achievable Control Technology ("MACT") standards to hazardous air pollutants. 42 U.S.C. § 7412(f)(1). Section 112(f)(1) contemplates a six-year period of study and instructs EPA to provide Congress with recommendations for legislation on residual risks at the conclusion of that period:

> Not later than 6 years after November 15, 1990, the Administrator shall investigate and report . . . to Congress on—
>
> (A) methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under this section after the application of standards under subsection (d); . . . [and]
>
> (D) recommendations as to legislation regarding such remaining risk.

Id. Section 112(f)(1) thus specifically contemplates further congressional action on residual risk standards.

In section 112(f)(2), Congress set forth a contingency plan "[i]f Congress does not act on any recommendation submitted under paragraph (1) . . . ." *Id.* § 7412(f)(2)(A). That second reference is critical. "If," and only if, Congress fails to act on EPA's recommendation, EPA is required to evaluate and, if appropriate, "promulgate" residual risk standards for a source category "within 8 years" of the

issuance of the corresponding MACT standards for that source category. 42 U.S.C. § 7412(f)(2)(A); *see also id.* § 7412(f)(2)(C) ("8 years after promulgation").

Congress was even more specific about a subset of these source categories. In section 112(f)(2)(C), Congress provided: "In the case of categories or subcategories for which standards under subsection (d) are required to be promulgated within 2 years after November 15, 1990, the Administrator shall have 9 years after promulgation of the standards under subsection (d) to make the determination [whether to promulgate residual risk standards] and, if required, to promulgate the standards under this paragraph." This is a reference to section 112(e)(1)(A), which provides that EPA must ensure that "emission standards for not less than 40 categories and subcategories (not counting coke oven batteries) shall be promulgated not later than 2 years after November 15, 1990." As with the default mandate to act within 8 years of promulgation of the section 112(d) standards, this specific mandate makes no provision for recurrence; it is a one-time requirement for each source category.

To sum up, Congress reserved for itself primary authority to dictate residual risk review and the promulgation of standards. Congress delineated a specific, limited contingency plan through which EPA would regulate (if necessary) based on residual risk if Congress did not act, but only one time per source category. As the statutory text makes clear, that was never the primary option.

In 1999, EPA complied with section 112(f)(1) by delivering its residual risk report to Congress. EPA, Residual Risk Report to Congress 1999, https://tinyurl.com/546ceek5. But Congress never acted. So EPA has since performed "residual risk reviews" for various source categories under section 112(f)(2). EPA conducted a residual risk review for the source category at issue in the present rulemaking, ethylene oxide sterilizers, eighteen years ago, in 2006. *See* 67 Fed. Reg. 17,712 (Apr. 7, 2006).

2. If Congress wanted to authorize more than one iteration of residual risk review, it would have said so.

That Congress never intended EPA to retain open-ended authority to regulate residual risk standards in perpetuity is confirmed by section 112(f)(2)'s description of EPA's back-up authority as a one-time event. Under section 112(f)(2), EPA "shall *promulgate*" standards for each source category or subcategory concerned. 42 U.S.C. § 7412(f)(2)(C) (emphasis added). And if EPA decides to set a residual risk standard, it must do so *within eight years* of the promulgation of the corresponding MACT standard. *Id.* This plain statutory language contemplates a single, time-limited regulation period. Nothing more is authorized—certainly not the imposition of further review at some indefinite later date.

EPA does not appear to contest that section 112(f)(2) describes a one-time event. *See* 89 Fed. Reg. at 24,094 ("While CAA section 112(f)(2) requires only a one-time risk review . . . ."). Instead, it insists that section 112(f)(2) "does not limit

[its] discretion or authority to conduct *another* risk review should [it] consider that such a review is warranted." *Id.* (emphasis added). But if Congress wanted to grant EPA authority to conduct subsequent risk reviews that could result in new regulations, Congress knew how to do it. That it failed to explicitly grant that authority is damning to the Agency's position. *See Pub. Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 816–17 (D.C. Cir. 2008) (declining to "add[] words that are not in the statute that the legislature enacted"); *see also Nat. Res. Def. Council v. Regan*, 67 F.4th 397, 402 (D.C. Cir. 2023) (explaining that reading an additional grant of authority into the Safe Drinking Water Act "would be to contravene the statute's clear language and structure and 'nullif[y] textually applicable provisions meant to limit [EPA's] discretion'" (citing *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008)).

Indeed, Congress demonstrated that it knew how to explicitly authorize the kind of ongoing revision authority that EPA now claims under section 112(f). Prior to section 112(f), subsection 112(d)(6) provides:

> The Administrator shall review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years.

42 U.S.C. § 7412(d)(6). And section 112(d)(6) is not alone. Similar provisions abound in the CAA. *See* 42 U.S.C. § 7409(d) (review and revision of ambient air quality standards); *id.* § 7411(b)(1)(b) (review and revision of new source

performance standards); *id.* § 7511b(b) (requirement to periodically review and if necessary update control technology guidelines); *id.* § 7521(a)(1) (authority to revise from time to time motor vehicle emission standards); *id.* § 7521(a)(2)(B) (authorizing revision of pre-1990 standards for heavy duty vehicles and engines); *id.* § 7521(b)(1) (authorizing revision of any standard prescribed under Section 202 as needed to protect public health or welfare, taking costs, energy, and safety into account); *id.* § 7547(a)(3)–(4) (revision from time to time of standards for nonroad engines).

In light of these several nearby provisions, Congress's failure to include a provision like this in section 112(f), or otherwise grant authority for further review, is very strong evidence that it did not intend to license subsequent residual risk reviews by EPA. Put otherwise, the structure and text of section 112 and of other CAA provisions show that section 112(f) empowers EPA only to do a one-time residual risk review for a source category, and not to engage in multiple risk reviews. Aside from the one-time risk review provided by section 112(f), the sole vehicle whereby EPA may revise its section 112(d) regulations is through section 112(d)(6), which expressly authorizes recurring rounds of technology-based reviews and (when necessary) revisions of those regulations. Indeed, "when Congress includes particular language in one section of a statute but omits it in another," courts

"presume that Congress intended a difference in meaning." *Loughrin v. United States*, 573 U.S. 351, 358 (2014).

Instead, Congress reserved to itself the decision of whether to require additional residual risk reviews.

B. Significantly, section 112(f)(2) provides no standards or guardrails that would guide or constrain further regulation.

Nothing in section 112(f)(2) guides or places any limits on EPA's claimed authority to revise residual risk standards after their initial promulgation. The provision provides no process or criteria for reopening or repeating a one-time residual risk review. And it likewise provides no standards for determining how to conduct such a new residual risk review.

The complete absence of any such guardrails not only provides further evidence that Congress never intended to license subsequent reviews through section 112(f)(2) at all, but it also demonstrates the breadth of EPA's claimed power under its interpretation of the provision. If the Court were to adopt EPA's reading of section 112(f)(2), EPA would enjoy complete discretion to dictate subsequent reviews. EPA could reopen residual risk review whenever it chooses and for whatever reason it chooses.

That cannot be right. It is well settled that "Congress . . . does not . . . hide elephants in mouseholes." *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) (finding it "implausible that Congress would give to the EPA . . .

the power to determine whether implementation costs should moderate national air quality standards" through "modest words"). Indeed, in a recent case this Court reaffirmed the "long-standing rule of interpretation" that "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Heating, Air Conditioning & Refrigeration Distributors Int'l v. EPA*, 71 F.4th 59, 67 (D.C. Cir. 2023) (citing *Whitman*, 531 U.S. at 468). The Court explained that "[o]rdinary readers of English do not expect provisions setting out math equations to empower an agency to prescribe other 'fundamental details of a regulatory scheme.'" *Id.* (citing *Whitman*, 531 U.S. at 468); *see also, e.g.*, *Turkiye Halk Bankasi A.S. v. United States*, 598 U.S. 264, 274 (2023) (applying *Whitman* principle to Foreign Service Immunities Act in international criminal dispute); *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 465 (2017) (applying *Whitman* principle in bankruptcy case); *Banks v. Booth*, 3 F.4th 445, 449 (D.C. Cir. 2021) (applying *Whitman* principle to Prison Litigation Reform Act in civil rights dispute).

So too here. Section 112(f)(2) delineates a second-best alternative to congressional action on residual risk, contemplating a single, time-limited period for EPA review. Ordinary readers can see that this one-time back-up plan does not supply "fundamental details of [the] regulatory scheme" that would license unbounded regulation for all time.

II. The regulatory uncertainty caused by EPA's interpretation of section 112(f) would stifle investment and jobs in communities across the country.

Businesses large and small depend on stable, predictable regulatory regimes to survive, plan, and grow. When regulatory standards are clear, the business community can work with federal and state governments to achieve common objectives. EPA's historic regulation of ethylene oxide proves the point. As detailed below, the ethylene oxide industry has cut emissions by over forty percent in the United States in the last decade.

But allowing EPA to interpret section 112(f)(2) as an open-ended license to regulate threatens this success story. EPA's novel assertion of authority would impose substantial and unpredictable burdens on producers and users of ethylene oxide already bearing the heavy costs of existing regulations. And it would set a dangerous precedent, both for businesses subject to the broader residual risk review program and for the wider business community.

A. The existing Clean Air Act framework has successfully reduced emissions of air pollutants, including ethylene oxide.

In the nearly thirty-five years since Congress overhauled the CAA in 1990, businesses have curbed air-pollutant emissions substantially. In response to legal and regulatory requirements—and to protect public health and the environment and respond to community and stakeholder concerns—businesses have installed emissions-control technologies and taken steps to reduce their emissions.

As a general matter, these efforts have worked, leading to drastic improvements in air quality. For example, EPA data shows that "between 2005 and 2021, emissions of sulfur dioxide (SO2) and nitrogen oxides (NOX) from electricity generation were reduced by 91% and 79%, respectively." *Something to Celebrate on Earth Day*, U.S. CHAMBER OF COMMERCE GLOBAL ENERGY INSTITUTE (April 22, 2022) ("*Something to Celebrate*"), https://tinyurl.com/scwvszd7. And for the industrial sector in particular, EPA's National Emissions Inventory shows that "emissions of SO2, NOx, and fine particulate matter (PM2.5)" for fuel combustion "have declined by 81%, 62%, and 29%, respectively, since 2000." *Id.* Chemical air releases declined by 26% from 2013 to 2022. EPA, Air Releases (March 2024), https://tinyurl.com/7fybd83n.

Businesses using and producing ethylene oxide are no exception. Indeed, EPA data shows that between 2011 and 2020 ethylene oxide led all other industrial chemicals with a massive emissions reduction of 54%. *Something to Celebrate*, https://tinyurl.com/scwvszd7 More recent data paints a similar picture. Between 2013 and 2022, "releases of ethylene oxide to air decreased by 124,000 pounds (- 43%)." EPA, Toxic Release Inventory National Analysis, Ethylene Oxide Releases Trend (March 2024), https://tinyurl.com/ywmfec5r.

A key driver of these successes is the clarity and certainty that predictable regulatory schemes provide. When administrative agencies act within the limits of

their statutory authority and apply clear standards that the business community knows about far in advance, businesses can plan ahead, budget for regulation, and work with federal and state governments to implement emissions reduction efforts.

B. Greenlighting cumulative regulation, under a statutory provision that allows only for one-time regulation, would substantially undermine businesses' long-term plans and deter important investments.

In contrast to the successes that can be achieved when businesses operate in a stable and predictable regulatory environment, new and unexpected regulation can devastate businesses. As discussed above, EPA's interpretation of section 112(f) transforms a discrete grant of one-time, residual authority into an open-ended license to promulgate residual risk standards at EPA's discretion. As section 112(f)(2) was not designed for this purpose, it is not surprising that the provision contains no standards that could help a business predict the timing or scope of any new regulation that EPA might try to attempt under its claimed authority. EPA's interpretation of the provision leaves businesses in the dark, unable to make informed calculations about the future.

It bears emphasis that EPA's assertion of authority under section 112(f)(2) has implications ranging far beyond the particular category of sources at issue in this case. If this Court upholds EPA's interpretation of section 112(f)(2), then any business subject to one of the over 140 source categories EPA has established under the Act's hazardous air program, or any business that relies on such a business, will

not know when or how EPA might decide to exercise the discretionary authority that it has arrogated to itself under section 112(f)(2). *See* EPA, National Emission Standards for Hazardous Air Pollutants (NESHAP) (last updated July 2024), https://tinyurl.com/mxc7rbks. More broadly, allowing EPA to assert this novel power under section 112(f)(2) will embolden EPA and other agencies to push the envelope in claiming authority to regulate.

That outcome would chafe against precedents from this Court and the Supreme Court. *See Heating, Air Conditioning & Refrigeration Distributors Int'l*, 71 F.4th at 67 (discussing the "long-standing rule of interpretation" that "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions") (citing *Whitman*, 531 U.S. at 468). Indeed, the Supreme Court's recent elimination of *Chevron* deference in *Loper Bright* drives home how unconstrained administrative discretion jeopardizes reliance interests. There, the Court emphasized that discretion to change statutory interpretations under *Chevron* had become "a license authorizing an agency to change positions as much as it likes." 144 S. Ct. 2244 at 2272. "*Chevron* thus allow[ed] agencies to change course even when Congress ha[d] given them no power to do so." *Id.*

EPA's unlawful enlargement of its own authority via section 112(f) presents the same kind of problem. EPA is claiming unbounded discretionary power to impose immense costs on regulated parties. As the Supreme Court incisively

observed in *Loper Bright*, that level of discretion would "leav[e] those attempting to plan around agency action in an eternal fog of uncertainty." *Id.*

C. The impacts of EPA's interpretation on sterilization and on the businesses that depend on it underscore the importance of correcting EPA's interpretation.

The harmful impacts that EPA's novel assertion of authority pose for industry writ large are illustrated by the serious consequences that the Rule stands to impose upon commercial sterilizers and the businesses that depend on them.

Commercial sterilization facilities play a vital role in the medical industry and other parts of the economy. Ethylene oxide sterilizes half of all medical devices in America. U.S. Food & Drug Administration, Sterilization for Medical Devices (Sept. 26, 2024) ("Sterilization for Medical Devices"), https://tinyurl.com/6kk259hk. It is used to sterilize an estimated ninety-five percent of all surgical kits. EPA, *Memorandum re: Ethylene Oxide (PC#042301): Use, Usage, Benefit, and Impacts of Cancellation* (Dec. 1, 2022), https://tinyurl.com/58uzucy4. For many devices, it "may be the only [substance] that effectively sterilizes and does not damage the device." Sterilization for Medical Devices, https://tinyurl.com/6kk259hk. And devices sterilized by ethylene oxide "can be found in many healthcare procedures from a standard blood draw during an annual physical to a complex surgical procedure such as an open-heart surgery."

Advanced Medical Technology Association, Comments on Proposed Rule at 2 (June 27, 2023) ("AdvaMed Comments"), https://tinyurl.com/4t885hd6.

Ethylene oxide is particularly valuable because it can sterilize medical devices in their final packaging, which increases efficiency and reduces labor costs. U.S. Small Business Administration, Office of Advocacy, Comments on Proposed Rule at 2 (June 23, 2023) ("SBA Comments"), https://tinyurl.com/48d32575. It can also be used on diverse materials, from metals and plastics to resins and bandages. *Id.* No viable alternatives to ethylene oxide exist for sterilization of a broad range of medical devices and equipment. *Id.*

Ethylene oxide is also used by herb-and-spice processors to eliminate food-borne pathogens. As with medical devices, ethylene oxide may be the only "viable option for the treatment of certain spices and spice forms." EPA, EPA-HQ-OPP-2013-0244, Ethylene Oxide: Proposed Interim Registration Review Decision Case Number 2275 70 (Mar. 28, 2023) ("Proposed Interim Registration Review").

EPA's surprise regulation of ethylene oxide via section 112(f)(2) jeopardizes access to critical sterilization services, especially because regulated parties have already successfully implemented the most effective control measures and each additional measure comes at higher costs as the standards move closer to zero. EPA has estimated, for example, that six of the country's twenty small business commercial sterilizers would need to spend over twenty percent of their annual

revenue to comply with the Rule. SBA Comments at 12 (discussing *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* (March 2023), https://tinyurl.com/4unkstj6). Four more small businesses would need to spend between ten and twenty percent of their annual revenue. *Id.* In light of these numbers, and other regulatory headwinds, "it is not unreasonable to believe that more than half of the small commercial sterilizers will exit the market" in the wake of the Rule. *Id.* at 13; *see also id.* at 6 ("By EPA's estimates, a substantial number of small entities will be facing compliance costs that threaten their viability.").

These consequences would reverberate around the economy. Loss of commercial sterilizing capacity would have a direct impact on medical device manufacturers and associated businesses, which depend on sterilizers to get their products to consumers in a safe condition. "Taking even a handful of facilities offline briefly would cause supply disruptions." AdvaMed Comments at 3. And without abundant sterilization options in the short term, some patients would lack access to the important medical devices needed for effective care. SBA Comments at 13; AdvaMed Comments at 2 ("Inability to use EtO would prevent the use of many lifesaving technologies that have advanced medical care over the past 50 years."). As the COVID-19 pandemic vividly illustrated, strong supply chains are

essential for avoiding public health crises in this country. And more recently, the widespread impacts of the closure of an important intravenous fluid factory following Hurricane Helene demonstrate how even isolated shocks to medical supply chains can impact patient care throughout the country and escalate quickly. *See* Sydney Lupkin, *Storm damage closes N.C. factory that makes vital hospital supplies*, NPR (Oct. 4, 2024), https://tinyurl.com/4ka95r8d. Indeed, EPA itself has recognized that disruption of the supply of ethylene oxide would result in "disruption to the medical device supply chain" at large, causing "a nationwide public health crisis." Proposed Interim Registration Review.

In the long term, loss of sterilization capacity could force domestic manufacturers to turn more often to foreign sterilization facilities. SBA Comments at 14. If shortages persist, those manufacturers could even move their own operations overseas to minimize costs and delays. *Id.* Germany's recent economic woes are instructive in this regard. Rising costs have discouraged investment, dampened productivity, and ultimately driven industrial production out of the country. *See, e.g.*, Jim Vinoski, *German Deindustrialization Is A Wake-Up Call For U.S. Manufacturers*, FORBES (Mar. 4, 2024), https://tinyurl.com/yrzbzx6j. Strapping regulated parties with additional, unpredictable regulations in pursuit of regulatory goals could have the same impact on manufacturers and other businesses in United States supply chains.

If allowed to stand, EPA's unlawful assertion of authority under section 112(f)(2) promises serious disruption—not only for commercial sterilizers and associated industries, but for other businesses subject to Clean Air Act section 112 and, more broadly, for the business community generally. The Court should reject EPA's interpretation.

CONCLUSION

The petition for review should be granted and the Rule vacated.

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Respectfully submitted,

/s/ *Trevor S. Cox*

Trevor S. Cox
J. Pierce Lamberson
HUNTON ANDREWS KURTH LLP
Riverfront Plaza, East Tower
951 East Byrd Street
Richmond, VA 23219
(804) 788-8200

Charles H. Knauss
Matthew Z. Leopold
HUNTON ANDREWS KURTH LLP
2200 Pennsylvania Ave. NW
Washington, DC 20037
(202) 955-1500

Andrew R. Varcoe
Christopher J. Walker
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

Counsel for Amicus Curiae

CERTIFICATE OF COMPLIANCE

The undersigned counsel states that this document complies with Federal Rule of Appellate Procedure 29(a)(5) and this Court's briefing order dated September 4, 2024, because it contains 5,020 words, as counted by Microsoft Word, excluding the parts excluded by Federal Rules of Appellate Procedure 27(d)(2) and 32(f) and D.C. Circuit Rule 32(e)(1).

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/s/ *Trevor S. Cox*

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of October 2024, I caused a true and correct copy of the foregoing to be electronically filed with the Clerk of the Court of the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ *Trevor S. Cox*